

**REMARKS****I. Applicants' Invention and Preliminary Comments.**

Applicants' invention relates to the discovery that harvested bacteria have improved viability (compared with the same bacteria cultured in or grown on a medium not containing resistant starch) if they have been previously cultured in or grown on resistant starch and then subsequently incorporated into a product.

Claims 1-19 and 42-62 have been canceled and the subject matter of these claims has been rewritten as new claims 77-153 to address many of the rejections presenting in the Outstanding Action and to expedite allowance of those claims. No new matter is introduced thereby. A claim correlation chart is attached as Appendix 1. The application now presents four independent claims (77, 79, 81 and 88) from which all the remaining claims depend. First, each independent claim presents the limitations of now cancelled claim 2 in order to address the rejection under 35 USC §112 (second paragraph). Moreover, each of independent claims 77, 79, 81 and 88 present different aspects of the invention. Specifically, claim 77 recites that the resistant starch is selected from the type RS1, RS3 or RS4. Independent claim 79 recites that the resistant starch is derived from starch selected from the group consisting of rice, barley, wheat, legumes, bananas and combinations thereof. Independent claim 81 corresponds to original claim 6 and recites that the resistant starch is derived from a starch having an amylose content of at least 40% (w/w). Finally, new independent claim 88 corresponds to original claim 11 and recites that the starch is chemically, physically, and/or enzymically treated or modified.

In addition, claims 96-98, 111-113, 126-128, and 141-143 (which correspond to previously presented claims 18 and 19) have been amended in order to indicate the Latin names of microorganisms in italics in accordance with the Patent Office's suggestion.

**II. Outstanding Rejections**

Claims 1-19, 41-62 and 76 stand rejected under 35 U.S.C. §112 (second paragraph).

Claims 1-19, 41-62 and 76 stand rejected under 35 U.S.C. §102(b) over Masuda et al., U.S. Patent 5,143,845.

Claims 1-19, 41-62 and 76 stand rejected under 35 U.S.C. §102(b) over Brown et al. U.S. Patent 6,060,050 in light of evidence of McNaught et al. U.S. Patent No. 5,714,600.

Claims 1-19, 41-62 and 76 stand rejected under 35 U.S.C. §103(a) in view of the above references taken with Brown et al. *Food Australia*, 50(12), pages 603-610 (1998) ("Brown II").

Claims 1-19, 41-62 and 76 stand rejected under the judicially created doctrine of obviousness-type double patenting over Brown et al. U.S. Patent 6,221,350 ("Brown III").

### **III. Patentability Arguments**

#### **A. The Rejection Under 35 U.S.C. §112 should be withdrawn.**

The indefiniteness rejections should be withdrawn and new claims 77-153 need not be rejected because they have been modified in accordance with the Patent Office's suggestions. Specifically, previous claims 1 and 42 have been replaced with new claims 77, 79, 81, 88, 100, 115, 130 and 145 which have been amended to clarify the term "product" by incorporating the definition of "product" that appeared in previous claims 2 and 43.

Claims 41 and 76 are properly dependant on claim 20 which has been withdrawn from consideration as non-elected subject matter in the restriction requirement. Accordingly, applicants request that claims 41 and 76 also formally be subject to the same restriction as claim 20.

In addition, new claims 94, 109, 124 and 139 (which correspond to previous claim 15) have been amended to replace the phrase "in use" with the phrase "when incorporated in a product" to clarify that the claim is referring to the embodiment where the microbial preparation is incorporated into a product. In relation to the language of previous claim 15, the Examiner objected to several relative terms and the use of the term "stresses". Examples of the term "stresses" are provided in the specification at page 3, lines 26-31 and one skilled in the art would understand that these conditions refer to physical, chemical or biological

actions that usually result in a decrease in the viability of the microbes. Although some microbes can survive aeration and freeze-drying, they are still stressed during these processes and the overall viability over the total population is decreased. One of ordinary skill in the art would recognize that recovery processes that involve conditions of the type described in the claim will usually result in some decline in microbe viability, and therefore one of ordinary skill in the art would be apprised that the scope of the claim as conferred by the limitation "substantially resistant to stresses" is a reduction of the impact that these "stresses" have on the viability of the microbial preparation.

New claims 97, 112, 127, and 143 (which corresponds to previous claim 18) now recites a proper Markush group and clarifies that yeasts do not belong to the group of lactic acid bacteria. New claims 98, 113, 128, and 144 clarifies that *Lactobacillus*, *Lactococcus*, *Streptococcus* and *Leuconostoc* belong to the group of lactic acid bacteria.

In claims 99, 114, 129, and 145 (which correspond to previous claim 19), the term "*acidophilus*" has been changed to refer to the Latin genus *Lactobacillus* in accordance with the Patent Office's suggestion. This amendment finds support in the specification at page 2, line 18 describing "certain *bifidobacteria* and *acidophilus* strains." As used herein, the term "*bifidobacteria*" describes one major genus of lactic acid bacteria and the term "*acidophilus*" is intended to cover the other major genus, *Lactobacillus*.

Finally, claims 107, 123, 137, and 153 (which correspond to previous claim 62) have been amended to replace the phrase "used at" in favor of the phrase "added at a concentration of" and adding the phrase "total product" to refer to this concentration in accordance with the Patent Office's suggestion. This amendment finds support in the description at page 6, lines 17-30 describing the preferred concentrations of resistant starch in growth media and subsequent products.

The amended claims are now in accordance with the Examiner's suggestions and it is submitted that the rejection for indefiniteness should be withdrawn and each of claims 77-153 should be allowed.

**B. The Rejection Under 35 U.S.C. §102(b) over Masuda et al. Should be Withdrawn.**

The anticipation rejection over Masuda et al. should be withdrawn and not reentered as the claims have been rewritten in a manner which defines novel subject matter over that reference.

**1. Claims 77-78 and 94-108 Define Novel Subject Matter over Masuda et al.**

The anticipation rejection of claims 1-19 and 42-62 under 35 U.S.C. §102(b) over Masuda et al. should be withdrawn and need not be made against new claims 77-78 and 94-108 because Masuda et al. do not disclose harvested microbes which have been grown or cultured in a resistant starch of type RS1, RS3, or RS4 much less that such microbes have an increased survival/recovery rate as compared with the same microbes grown or cultured without resistant starch.

**2. Claims 79-80 and 109-123 Define Novel Subject Matter over Masuda et al.**

The anticipation rejection of claims 1-19 and 42-62 under 35 U.S.C. §102(b) over Masuda et al. should be withdrawn and need not be made against new claims 79-80 and 109-123 because Masuda et al. do not disclose harvested microbes which have been grown or cultured in a resistant starch from rice, barley, wheat, legumes, bananas, or combinations thereof, or that such microbes have an increased survival/recovery rate as compared with the same microbes grown or cultured without resistant starch.

**3. Claims 81-87 and 124-137 Define Novel Subject Matter over Masuda et al.**

The anticipation rejection of claims 1-19 and 42-62 under 35 U.S.C. §102(b) over Masuda et al. should be withdrawn and need not be made against new claims 81-87 and 124-137 because Masuda et al. do not disclose harvested microbes which have been grown or cultured in a resistant starch derived from a starch having an amylose content of at least 40% (w/w), or that such microbes have an increased survival/recovery rate as compared with the same microbes grown or cultured without resistant starch.

**4. Claims 88-93 and 138-153 Define Novel Subject Matter Over Masuda et al.**

The anticipation rejection of claims 1-19 and 42-62 under 35 U.S.C. §102(b) over Masuda et al. should be withdrawn and need not be made against new claims 77-153 because Masuda et al. do not disclose harvested microbes which have been grown or cultured in a resistant starch that is chemically, physically, and/or enzymatically treated or modified, or the Applicants' discovery that such microbes have an increased survival/recovery rate as compared with the same microbes grown or cultured without resistant starch.

**C. The Rejection Under 35 U.S.C. §102(b) over Brown et al. and McNaught et al. should be withdrawn.**

The anticipation rejection of claims 1-19 and 42-62 under 35 U.S.C. §102(b) over Brown et al. should be withdrawn and need not be made against new claims 77-153 because Brown et al. do not disclose Applicants' discovery that harvested microbes which have been grown or cultured in a resistant starch have an increased survival/recovery rate as compared with the same microbes grown or cultured without resistant starch. Instead Brown et al. discloses that bacteria grown or cultured on conventional media (*see* col. 7, line 38) can better survive in the gastrointestinal tract when they are ingested with resistant starch. (*See* experiment 3 at cols. 11-12). It does not, however, disclose that culturing bacteria with resistant starch outside the gastrointestinal tract can produce a microbial preparation with an increased survival/recovery rate.

McNaught et al. discloses a resistant maize starch having more than 80% amylase content which may be relevant to certain dependent claims but fails to make up for the deficiencies of Brown et al. with respect to the independent claims. Specifically, McNaught does not disclose growing or culturing the bacteria on a medium of resistant starch and then harvesting the bacteria and incorporating the bacteria in a product. Accordingly, claims 77-153 are novel over Brown et al. and should be allowed.

**D. The Rejection Under 35 U.S.C. §103(a) over Masuda et al. and Brown et al. taken with Brown II et al. and McNaught et al. should be withdrawn.**

The obviousness rejection of claims 1-19 and 42-62 under 35 U.S.C. §103(a) over the above references should be withdrawn and need not be made against new claims 77-153 because Masuda et al. fail to teach that culturing bacteria on resistant starch will result in the increased survival/recovery rate of bacteria as compared with the same microbes grown or cultured without resistant starch.

Specifically, Masuda et al is directed to the preparation of a beneficial bacterial formulation to promote health in the gastrointestinal tract. The reference discloses symbiotic combinations of saccharifcating bacteria (SB) and butyric acid producing bacteria (BB) with lactic acid producing bacteria (LB) and teaches that after spore formation, their heat stability, dry stability, and drug stability are enhanced (col. 2, lines 53-55). Thus Masuda et al. teach that SB and BB should be added to a product after spore formation rather than before spore formation to have better stability in the product.

While Masuda discloses the presence of potato starch in media for culturing the bacteria (*see* Example 2 at col. 5), it does not teach that culturing bacteria in the presence of potato starch specifically, or resistant starch generally, will promote stability of bacterial preparations so cultured. Specifically, the Masuda reference fails to make any reference to resistant starch. Moreover Masuda teaches that any of a variety of carbohydrates including cornstarch and soluble starch may be used as a carbon source (col. 4 lines 24-33). Accordingly, there is no teaching in Masuda et al. that resistant starch be selected from any of a variety of suitable carbohydrate sources much less that a superior microbial preparation would be obtained by the selection of a resistant starch.

Brown et al, Brown II et al. and McNaught et al. fail to make up for the deficiencies of Masuda et al. with respect to the *in vitro* culturing of bacteria because they are directed to bacterial probiotics within the gastrointestinal (GI) tract. Brown II et al., like Brown et al., teach that harvested bacteria are more viable when used in a product in combination with resistant starch which can act as a growth medium in the bowel (*See* Brown et al. experiment 3 at cols. 11-12; Brown II p. 607), but do not teach that the bacteria which have been previously cultured on resistant starch will be more viable after such culturing. (Brown et al.

col. 7, line 38; Brown II p. 607) Accordingly, the secondary references fail to make up for the deficiencies of Masuda et al. with respect to teaching the beneficial effects of resistant starch in the production of a microbial preparation.

**E. The Rejection Under the Judicially Created Doctrine of Obvious-Type Double Patenting over Brown et al. should be withdrawn.**

Finally, the obviousness-type double patenting rejection over claims 1-12 of U.S. Patent No. 6,221,350 should also be withdrawn because claims 1-12 of U.S. Patent No. 6,221,350 are directed to a probiotic composition comprising microorganisms and a resistant starch carrier which acts as a growth or maintenance medium for the microorganisms in the gastrointestinal tract. U.S. Patent No. 6,221,350 neither discloses nor teaches production of a microbial preparation of harvested microbes by culturing on a medium based on or containing resistant starch. Accordingly, the obviousness type double patenting rejection should be withdrawn and each of claims 77-153 should be allowed.

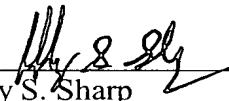
**CONCLUSION**

For all of the foregoing reasons, the applicant's respectfully request that the rejections should now be withdrawn and an early notice of all pending claims is respectfully solicited. Should the Examiner wish to discuss any issues of form or substance in order to expedite allowance of the pending application, he is invited to contact the undersigned attorney at the number indicated below.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

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Respectfully submitted,

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